REMARKS

Claims 29 and 41-61 are pending in the application. Claims 29 and 41-61 were finally rejected in the July 28, 2005 Office Action.

Claims 41, 43, and 45 stand rejected for allegedly failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. It appears this rejection is still outstanding.

Claims 41-43, 46-56 were rejected for alleged indefiniteness under 35 U.S.C. § 112, second paragraph. Applicants note with appreciation the indication in the April 28, 2006 Advisory Action that this rejection has been overcome by Applicants' latest response.

Claims 29 and 41-56 stand rejected under 35 U.S.C. §§ 101 and 112 for allegedly failing to satisfy the utility requirement under section 101 and consequently the enablement and written description requirements of section 112.

Claims 57-61 stand rejected under 35 U.S.C. §§ 101 and 112 for allegedly failing to satisfy the utility requirement under section 101 and consequently the enablement and written description requirements of section 112, as maintained from the February 10, 2005 Office Action.

This response is being filed along with an RCE in lieu of an Appeal Brief. The Notice of Appeal has been timely filed, and an appropriate petition for extension of time is being filed herewith.

Claim Rejections

A. The 35 U.S.C. § 112, first paragraph, rejection of claims 41, 43, and 45 has been overcome by previous amendment.

Claims 41, 43, and 45 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. It is unclear from the April 28, 2006 Advisory Action whether this rejection has been overcome. In the interest of completeness, Applicants resubmit their remarks here with regard to the previous amendments. The rejection

objects to the amended language "associated with sensorimotor processing or arousal disorder." Applicants have deleted this language. Applicants respectfully submit that these deletions are made as an administrative expedient and that the specification clearly supports the association of hRUP35 with the thalamus and sensorimotor processing and arousal disorders. The discussion, however, is moot in light of the amendments presented in Applicants' December 22, 2005 response. Clear indication that the rejection has been withdrawn is respectfully requested.

B. Claims 29 and 41-61 satisfy the requirements of 35 U.S.C. §§ 101 and 112

The rejection of claims 29, and 41-61 under 35 U.S.C. § 101 and 112 has been maintained. Applicants respectfully assert that the rejection should be withdrawn.

1. The utility rejection based on 35 U.S.C. § 101 should be withdrawn.

The utility requirement finds its basis in the constitution, which permits the granting of patent to promote the useful arts, and in 35 U.S.C. § 101, which provides for patent protection for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

The Patent Office has promulgated a series of guidelines concerning the utility requirement, which can be found in MPEP § 2107 *et seq.*

a) Applicants' Utility is specific, substantial and credible, as required under 35 U.S.C. § 101.

Applicants address the requirements of 35 U.S.C. § 101 to assert a specific, substantial and credible utility, in a straightforward manner similar to the Revised Interim Utility Guidelines Training Materials (hereafter "Training Materials") available at http://www.uspto.gov/web/menu/utility.pdf, which pose the questions of specificity, substantiality and credibility in turn. Applicants turn to Example 12 of the Training Materials as a particularly relevant guide.

1) Has the Applicant made any assertion of utility for the specifically claimed invention?

YES. Page 8 of the Action admits "Applicant has asserted utilities for the specifically claimed invention of claims 29, 41-56." The Action does not characterize these asserted utilities. Applicants respectfully assert that at least one of these utilities parallels that set forth in

Example 12, namely for use in methods of identifying materials which bind to hRUP35, i.e. screening methods. Thus, at least one utility has been asserted.

2) Is the asserted utility specific?

YES. Here, Applicants simply paraphrase the answer in Guidelines Example 12:

"In this case, the method of identifying materials which bind to a specific receptor, namely [hRUP35] . . . [is a method that is] not applicable to the general class of receptors [or even the subclass of GPCRs]. Therefore, there is an asserted specific utility for the claimed invention." (modifications added.)

Applicants believe the simplicity of this analysis is a blessing and the conclusion with respect to the present case is indisputable in light of the close similarity to Guidelines Example 12, which clearly indicates that neither a biological function nor a disease state was disclosed in the Example specification, and, thus, clearly indicates neither is required to establish a specific utility. Thus, although Applicants have disclosed a biological function or disease state, such disclosure is not relevant to the question of specific utility.

Applicants' asserted utility is specific.

3) Is the asserted utility substantial?

YES. Here the facts of the present case begin to differ more significantly from those of Training Materials Example 12. Particularly, Training Materials Example 12 specifically states that no disease or condition is disclosed by the specification. In sharp contrast, Applicants have disclosed thalamus-related disorders, specifically, sensorimotor processing and arousal disorders. The Example does, however, provide some much needed guidance. In this case, the discussion of substantiality with respect to Training Materials Example 12, claim 2, seems to flesh out the requirement more than the discussion related to claim 1. (Both discussions focus on the fact that the Example does not disclose any disease or body condition.) The Training Materials on page 67 state:

> Specifically, the method essentially is a method of identifying a material, i.e., those materials which bind to receptor A. Thus, to determine whether or not this method has a 'substantial' utility, it must be determined whether or not the material that binds to receptor A itself has a 'substantial utility.' Here, the only utility asserted for the identified materials is a therapeutic to effect control over receptor A. Since neither the specification nor the art of record disclose any disease states or conditions associated with receptor A, the asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a 'real world' context of use. Treating an unspecified, undisclosed disease or condition clearly would require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use. (citations omitted)

This language is repeated nearly verbatim in the current rejection. The present case, however, is easily distinguished from that set forth in Training Materials Example 12. The present utility is not merely to effect therapeutic control over hRUP35, but rather to treat sensorimotor processing and arousal disorders via that control. The present case clearly links hRUP35, through its expression in the thalamus, to sensorimotor processing disorders and arousal disorders, which were well known to those of skill in the art (see, Goodman & Gilman's The Pharmacological Basis of Therapeutics (1996) 9th Ed, McGraw-Hill, p.465; Elble (1998) Movement Disorders, 13:35-39, Portas et al (1998) The Journal of Neuroscience, 18:8979-8989; and Jeljeli et al. (2000) Neuroscience Research, 38:155-164). It appears to Applicants that the Office's heavy reliance on its position that hRUP35 is not associated with sensorimotor processing and arousal disorders is misplaced and completely lacking in evidentiary support. Consequently, the conclusion that the utility is for treating an unspecified, undisclosed disease or condition is flawed. The facts set forth in the specification or otherwise available to those of skill in the art, and simple logic lead to the conclusion that hRUP35 is associated with sensorimotor processing and arousal disorders, and, thus, a specified, disclosed disease or condition has been associated with hRUP35. Those of skill in the art would readily recognize that hRUP35 is useful for screening candidate compounds for treating diseases or disorders of the thalamus, for example sensorimotor processing disorders and arousal disorders. Applicants specification and/or reasoning herein establish (references to paragraphs are to the number paragraphs of the corrected published application US2003-0139588 A9):

a. hRUP35 is expressed in the thalamus (see Table E);

b. proteins located/expressed in the thalamus are associated with sensorimotor processing and arousal (see paragraph [0075]);

c. expression in the thalamus is associated with sensorimotor processing and arousal disorders (see paragraph [0075] and paragraph [0214] following Table E); and

d. hRUP35 expression results in increased levels of IP_3 in thalamus (see Fig. 2; OA, p. 9).

Therefore, logically, it follows that hRUP35, through its expression in the thalamus, is associated with sensorimotor processing and arousal disorders and, therefore, can be used to screen for compounds to treat such disorders.

Thus, compounds identified by the screening methods can be used to treat sensorimotor processing and arousal disorders. Such disorders are specific and substantial. Thus, the asserted utility of identifying compounds that bind to hRUP35 to treat these disorders is substantial.

4) Is the utility credible?

YES. The Action does not directly address credibility as a separate element. Training Materials Example 12, likewise, does not reach the question of credibility, in part, we suspect, because it settles the question of utility in its analysis under the substantial requirement.

With respect to credibility, the MPEP § 2107 and the case law are clear that once Applicants have asserted a specific and substantial utility, a presumption of utility must be rebutted by the Office with evidence of reasons why one of skill in the art would have doubted the utility. Here, the Office has provided no evidence as to why one of skill in the art would have questioned either the facts or logic underlying Applicants' asserted utility, and, thus, has not properly set forth a *prima facie* case of lack of utility.

Although Applicants maintain that the Office has yet to provide evidence sufficient to support a *prima facie* case of lack of utility, we note that given Applicants' prior response, the Office must assess utility in light of the totality of the record. MPEP § 2107 directs that

> **Only** where the **totality of the record** continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained. (Emphasis added.)

The Office must establish that it is more likely than not that a person of ordinary skill in the art would not consider the utility asserted by Applicants to be specific and substantial. Applicants

respectfully assert that the totality of the record shows that those of skill in the art would have been more likely than not to consider Applicants' utility to be specific and substantial.

b) Applicants have a presumption of utility.

Applicants' maintain that the original rejection did not satisfy the requirements for a *prima facie* showing of a lack of utility. MPEP § 2107.02 III.A. makes it clear that the Office must presume that Applicants' statements of utility are true, and that the Office should give deference to Applicants' understanding of the invention when the statements of utility are examined. The MPEP specifically states "Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicants." "Clearly, Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons."

c) Only where the totality of the record shows that one of skill in the art would have had doubted Applicants' utility can the presumption be overcome.

Furthermore, the MPEP § 2107.02 III.A continues, stating "to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e. "question") the truth of the statement of utility. The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. Thus, to uphold the rejection, the totality of the evidence must show that it is more likely than not that Applicants' statements of utility are false. Applicants respectfully assert that the totality of the evidence shows that Applicants have asserted a specific, substantial and credible utility and the Office has not provided evidence that it is more likely than not that Applicants' statements of utility are false.

d) The scientific literature supports Applicants' utility and certainly does not lead one skilled in the art to question it.

Those of skill in the art would not doubt Applicants' utility, because earlier literature indicates that GPCRs similarly expressed in the thalamus modulate sensorimotor processing.

One skilled in the art would be led to believe similar results would occur with other GPCRs so expressed. Since filing, at least one recent publication has confirmed Applicants' utility. Thus, the scientific literature, both before and after filing, supports Applicant's utility and certainly does not make it more likely than not that Applicants' statements would have been viewed as false.

Earlier publications would not lead those of skill in the art to question Applicants' utility.

Applicants have disclosed in Fig. 2 that hRUP35 expression leads to increased intracellular IP_3 levels. Those of skill in the art, at least as early as 1994, would have recognized that a GPCR expressed in thalamus can modulate sensorimotor processing and arousal and, furthermore, that a GPCR expressed in thalamus that stimulates IP_3 metabolism (for example increases an intracellular level of IP_3) can modulate sensorimotor processing and arousal. Applicants submit herewith a copy of Salt and Eaton, Neurochem Int (1994) 24:451-458, which teaches that a GPCR known to stimulate IP_3 metabolism modulates sensory response in thalamus, for example response evoked by noxious thermal stimulation of the peripheral receptive field (see, e.g. p. 455, lines 1-28 of the Discussion.) This teaching is further supported by Miyata et al., J Neurosci (2003) 23:8098-8108 (also submitted herewith). These references support the credibility of Applicants' utility, and make it more likely than not that one skilled in the art would not have questioned Applicants' asserted utility.

The Advisory Action states that there is no indication that hRUP35 would evoke noxious thermal stimulation. Such an indication is not required, since the burden is on the Office to provide a reason why one of skill in the art would doubt the applicants' assertions. Those of skill in the art would note that GPCRs expressed in the thalamus can and do modulate sensorimotor processing and arousal. Thus, those of skill would have less reason to doubt Applicants' assertion that hRUP35, which is expressed in the thalamus, is useful in treating sensorimotor processing and arousal disorder. Accordingly, the cited references actually support Applicants' position. The Office still has not provided any reason to doubt Applicants' utility.

Recent publication confirms Applicants' utility.

Abstract #328 from the February 2006 Keystone Symposium (enclosed) discloses GPR139, which is identical to RUP35. As noted above, Applicants have always maintained that hRUP35 is useful in treating sensorimotor processing and arousal disorders, such as tremor

disorder, action tremor disorder, disorders of impaired motor coordination and impaired cognitive performance. The Abstract indicates that GPR139 (RUP35) is associated with motor coordination. In particular, reduction of GPR139 function is associated with impaired motor coordination. Thus, the reference clearly substantiates Applicants' position that hRUP35 is associated with such disorders. Applicants' utility is *not* directed to an unspecified, undisclosed disease or disorder, as suggested in the Action.

e) None of the Examiner's contentions, viewed under the totality of the record, would lead one skilled in the art to question Applicants' utility.

The Office has repeated several themes throughout the history of this case. Even in light of the Examiner's contentions, those of skill in the art would not have a reason to doubt that Applicants' assertion that the GPCR hRUP35 could be used to screen for compounds useful in treating sensorimotor processing and arousal disorders. Applicants have presented facts indicating that hRUP35 is expressed in the thalamus and that expression in the thalamus is associated with sensorimotor processing and arousal. For this reason alone, the Office's allegations are not sufficient to rebut the truth of Applicants' statements of utility. The repeated themes of the rejection are either unimportant in the discussion of specific and substantial utility, or inaccurate.

Despite the Office's repeated statements, their own Training Materials make it clear that there need not be a known or disclosed activity to have a specific and substantial utility, Applicants, nonetheless, have provided disclosure of such activity in the form of expression data.

As discussed above, to have a specific and substantial utility, there need not be a known or disclosed activity. However, Applicants have disclosed in Fig. 2 that hRUP35 expression leads to increased intracellular IP_3 levels. Those of skill in the art, at least as early as 1994, would have recognized that a GPCR expressed in thalamus can modulate sensorimotor processing and arousal and, furthermore, that a GPCR expressed in thalamus that stimulates IP_3 metabolism (for example increases an intracellular level of IP_3) can modulate sensorimotor processing and arousal. Applicants submit herewith a copy of Salt and Eaton, Neurochem Int (1994) 24:451-458, which teaches that a GPCR known to stimulate IP_3 metabolism modulates sensory response in thalamus, for example response evoked by noxious thermal stimulation of the peripheral receptive field (see, e.g. p. 455, lines 1-28 of the Discussion.) This teaching is

further supported by Miyata et al., J Neurosci (2003) 23:8098-8108 (also submitted herewith). These references support the credibility of Applicants' utility, and make it more likely than not that one skilled in the art would not have questioned Applicants' asserted utility.

Despite the characterization in the April 28, 2006 Advisory Action, Applicants' assertion that hRUP35 is useful in treating sensorimotor processing disorders and arousal disorders is not merely recited in a "laundry list" lacking specific disclosure.

Page 19, paragraph [0075] of Applicants' specification clearly indicates that "For example and not limitation, proteins located/expressed in areas of the thalamus are associated with sensorimotor processing and arousal (see, Goodman & Gilman's, The Pharmacological Basis of Therapeutics, 9th Edition, page 465 (1996))." Accordingly, it is clear that expression in the thalamus is linked to sensorimotor processing and arousal disorders. Applicants have also shown that hRUP35 is expressed in the thalamus. Thus, those of skill in the art would recognize, as stated by Applicants, that hRUP35 is useful in treating diseases of the thalamus, such as sensorimotor processing and arousal disorders.

The Office repeatedly mischaracterizes Applicants' disclosure by indicating hRUP35 is not associated with a disease or disorder.

The specification, at p. 19, paragraph [0075] and elsewhere, associates sensorimotor processing and arousal with hRUP35 through its expression in the thalamus. Those of skill in the art would appreciate that hRUP35's expression in the thalamus and accompanying increase in intracellular IP_3 would make it useful in treatment of diseases/disorders of the thalamus such as sensorimotor processing and arousal disorders.

The lack of a particular function or biological significance is not fatal to Applicants' utility, especially in light of Applicants' clear disclosure and supportive documents.

The rejection at page 11 states, "The utilities asserted by Applicant are not specific or substantial." The bases for this conclusion are perhaps best summarized on page 6, which says (in reply to Applicants' prior response) "The utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the hRUP35 of the instant invention," and on page 11 which continues "the asserted utilities are essentially methods of testing for or for potentially treating unspecified, undisclosed diseases or conditions, which does not define a 'real world' context of use." The

Training Materials Example 12 explicitly finds a specific utility where the Example explicitly notes that no biological function or significance is disclosed. Accordingly, no disclosure of a biological function or significance is required to support a specific utility. Example 12 finds lack of a substantial utility because, unlike the present application, Example 12 is utterly silent with respect to any disease, disorder, or condition that can be treated by the receptor of Example 12. In sharp contrast, Applicants have disclosed diseases or disorders associated with hRUP35 both in the specification and through evidence and discussions presented in this response as well as previous responses. Any lack of biological function or significance is not fatal to Applicants' utility, in light of Training Materials Example 12 and the clear disclosure of a disease, disorder, or condition associated with the receptor as supported by the evidence of record.

Applicants do not rely solely on structural similarity to other GPCRs for utility.

While it is true that hRUP35 is a GPCR and, thus, has properties also attributable to other members of the group, the properties of hRUP35 are not based solely on its membership in the GPCR family. hRUP35 increases the level of intracellular IP_3, as exemplified in Fig. 2 by transfected 293 cells expressing recombinant hRUP35. Those of skill in the art viewing this data, coupled with the known expression in the thalamus would conclude that hRUP35 increases intracellular IP_3 in the thalamus. It is this expression and data, *inter alia*, that lead one skilled in the art to appreciate hRUP35's usefulness in treating sensorimoter processing and arousal disorders. Applicants do NOT rely solely on the fact that hRUP35 is a GPCR. This theme seems to be directed to the specific requirement of 35 U.S.C. § 101, which, as discussed above, is clearly met by Applicants.

Knowledge of a ligand for hRUP35 is not a requirement for utility.

Knowledge of the natural ligand for a receptor is NOT a requirement for utility under 35 U.S.C. § 101. Nor would those of skill in the art doubt an asserted utility merely because the natural ligand is unknown, indeed Applicants have previously noted that other well-known receptors (for example the niacin receptor) agonists of which have been identified and used for years without ever deorphanizing the receptor. Those of skill in the art would appreciate Applicants' teachings linking hRUP35 expression to the thalamus and, in turn, to thalamus-related disorders, specifically sensorimotor processing and arousal disorders. Given Applicants'

teaching, the lack of a natural ligand would not lead those of skill in the art to question the asserted utility.

Thus, an examination of the totality of the record supports a finding that those of skill in the art would be more likely to believe Applicants' asserted utility, and less likely to doubt that assertion. Accordingly, the rejection cannot be maintained.

Withdrawal of the 35 U.S.C. § 101, and accompanying 35 U.S.C. § 112 rejections is respectfully requested.

Applicants' Utility is Specific, Substantial, and Credible

Applicants respectfully submit that in light of the discussion above, it is clear that Applicants' asserted utility is specific, substantial, and credible.

2. The 35 U.S.C. § 112 rejections should be withdrawn.

Claims 29 and 41-61 stand rejected under 35 U.S.C. § 112, as lacking enablement since no utility has been recognized by the Office. In light of the discussion above, the rejection is moot, since a specific, substantial, and credible utility exists.

Claims 44-61 were rejected in the Final Office Action under 35 U.S.C. § 112 for allegedly failing to satisfy the enablement requirement, but no comment was made with respect to the rejection in the Advisory Action. Accordingly, Applicants' represent their prior reasoning. Paragraphs [0154] to [0157] teach how to obtain an endogenous nucleic acid sequence encoding an endogenous human RUP35 G protein-coupled receptor by carrying out RT-PCR using a pair of specific primers. Those of skill in the art will appreciate that RT-PCR employing the specific primers of SEQ ID NOs: 41 and 42 specifically amplify an endogenous nucleic acid sequence encoding an endogenous human RUP35 G protein-coupled receptor, as taught by the specification. SEQ ID NO:15 exemplifies such a nucleic acid; however, the teaching encompasses any endogenous nucleic acid encoding an endogenous RUP35 G protein-coupled receptor obtainable by carrying out RT-PCR using the pair of specific primers. For example, it encompasses an endogenous nucleic acid encoding a naturally occurring variant of SEQ ID NO: 16 that is amplifiable by the process. Applicants note that in the interest of clarity, the claim has been amended by replacing "obtainable" with "amplifiable." Thus, Applicants

respectfully assert that those of skill in the art would be able to make or use the claimed invention. The enablement requirement has been satisfied.

These 35 U.S.C. § 112 rejections were coupled with the 35 U.S.C. § 101 rejection and should be withdrawn in light of the arguments made with regard to the 35 U.S.C. § 101 rejections alone, and in light of the comments herein.

C. Applicants have satisfied the written description requirement under 35 U.S.C. § 112

Claims 44-61 are rejected under 35 U.S.C. § 112 for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of their invention. Applicants are not claiming "every polynucleotide known to man", but rather those which are amplifiable via RT-PCR with the specific pair of primers in the claim. Claim 44 has been previously amended to clarify that the desired nucleic acid sequence is amplifiable by RT-PCR employing the specifically claimed primers. As discussed above, this technique is applicable to any [endogenous] nucleic acid encoding an endogenous human [RUP35] G protein-coupled receptor obtainable by carrying out RT-PCR using the pair of specific primers. Applicants' specification teaches and provides examples of how this process is carried out (see paragraphs [0151] through [0157]). Thus, Applicants respectfully assert that those of skill in the art would readily appreciate that Applicants were in possession of the invention.

The Advisory Action focuses on "subtypes" or variants of hRUP35 and intertwines the issues discussed above with regard to association with a disease, and concludes "the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds." However, given time and perhaps the appropriate computer software, one skilled in the art could, in fact, envision each of the variants obtainable through the claimed process, and, therefore, can appreciate Applicants' disclosure as describing each and every variant. Thus, those of skill in the art would have appreciated that Applicants were in possession of the invention at the time of filing.

Additionally, those of skill in the art would recognize that all nucleic acid sequences encoding an endogenous human G protein-coupled receptor amplifiable by RT-PCR as embodied in Claim 44 are products, for example alleles, of a ***single*** RUP35 gene. With respect to the discussion concerning mGLUR1 (located on human chromosome 6) and mGluR5

(located on human chromosome 11), Applicants note that these are two *different* genes. Thus, the discussion in the Action seems irrelevant to the current invention, since it involves only a single RUP35 gene.

Applicants respectfully note that the Office appears to assume, incorrectly, that in RT-PCR every nucleotide position of the amplified product other than that fixed by the primers can be any nucleotide so as to encompass "trillions" of variants. One skilled in the art would be aware that the sequence of the amplified endogenous nucleic acid encoding a G protein-coupled receptor is highly constrained by the variability of the gene template used in RT-PCR in the form of cDNA, the gene being human RUP35 in the case of claim 44. Thus, those of skill in the art would not need to envision "trillions" of variants, but those obtainable using RUP35 as the gene template. This is a routine exercise in the art, and thus, one skilled in the art would recognize Applicants' were in possession of their invention on the filing date.

In light of the above reasoning, individually and collectively, Applicants respectfully submit that the claimed invention is fully enabled and described by the Applicants' specification. Withdrawal of the rejections under 35 U.S.C. § 112 is respectfully requested.

Applicants respectfully assert that each of the independent claims and all claims dependent therefrom satisfy the requirements of patentability. Withdrawal of the rejections is respectfully requested.

The Commissioner is hereby authorized to charge any fee or underpayment thereof or credit any overpayment to deposit account no. 50-1275.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

Respectfully submitted,
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